A18

102. (Amended) A method as defined in claim 101 where said endovascular prosthesis is a transluminally placed endovascular graft.

REMARKS

Any fees that may be due in connection with filing this paper, or during the entire pendency of this application, may be charged to Deposit Account No. 50-1213.

In the Specification

The amendments to the specification presented herein correct obvious typographical errors and produce grammatical clarity. The amendment to the paragraph on page 8, lines 10-16, of the specification deletes the article "a" for grammatical clarity. The amendment to the paragraph on page 13, lines 1-10, of the specification deletes the preposition "of" for grammatical clarity. The amendment to the paragraph on page 33, lines 1-6, of the specification adds the inadvertently omitted verb "may" for grammatical clarity. The amendment to the paragraphs on page 35, line 14, to page 36, line 3, of the specification deletes the article "a" for grammatical clarity. The amendment to the paragraphs on page 36, line 19, to page 37, line 13, of the specification replaces figure item number "640" with –1140–, replaces figure item number "655" with –1155–, and finds basis in Figure 11. The amendment to the paragraph on page 40, lines 3-7, of the specification adds the inadvertently omitted verb "overlap" for grammatical clarity. No new matter has been added.

In the Claims

The amendments to claims 1, 71, and 76, correct minor typographical errors and produce grammatical clarity. The amendments to claims 60, 89, and 102 correct claim dependency errors. No new matter has been added.

Included as an attachment is a marked-up version of the specification paragraphs and claims that are being amended, per 37 CFR §1.121.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: R. Whirley *et al.*

Serial No.: 09/679,725

Filed: October 4, 2000

For: *VIRTUAL PROTOTYPING AND TESTING FOR MEDICAL DEVICE DEVELOPMENT*

Art Unit: 2855
Examiner: Unassigned

ATTACHMENT TO THE PRELIMINARY AMENDMENT MARKED-UP PARAGRAPHS (37 CFR §1.121)

IN THE SPECIFICATION:

Please amend the specification as follows:

Please amend the paragraph on page 8, lines 10-16, as follows:

The following detailed description illustrates an embodiment of the invention by way of example, not by way of limitation of the principles of the invention. Various embodiments of the invention will be described by way of illustration with reference to various software tools, but it should be understood that other software tools that have [a] comparable capabilities of the mentioned tools may be used and other medical device aside from TPEGs may also be developed using this invention. In addition, although the invention is discussed in the context of prosthesis and specifically endovascular grafts, this is in no way meant to limit the scope of the invention.

Please amend the paragraph on page 9, lines 3-9, as follows:

Embodiments of the present inventions are particulary well suited for the development and testing of devices for use in the vascular system or other bodily systems that have stresses, strains, and deformations which are dynamic, or quasi-static, and cyclic in nature, e.g., the rhythmic pulsing of the arterial system resulting from variations in blood pressure from the [patent's]<u>patient's</u> beating heart and the resulting cyclic dynamic or quasi-static stresses, strains, and deformations these variations impart on the patient's arteries and medical devices disposed therein or thereon.

Please amend the paragraph beginning on page 9, line 14, through page 10, line 8, as follows:

Figure 1 is a block diagram showing one embodiment of a virtual prototyping system 105 for analyzing the use of a medical device constructed in accordance with an embodiment of the present invention. Figure 1 shows that a Geometry Generator 120 receives CT scan or MRI Data 110 as input. The Geometry Generator 120 then processes the CT scan or MRI data and outputs data, which are then received by the Mesh Generator 130 as input. The Mesh Generator, in addition to receiving the output of the Geometry Generator 120, also receives a Medical Device Model data 140 as input. The Medical Device Model 140 contains the geometry (geometric shape or geometric model) of the candidate medical device. Such model may be the complete candidate, a portion, or an element of the candidate medical device. Similarly, a portion or an element of the anatomical features, not the entire anatomy scanned, may be received by the Mesh Generator 130. The Medical Device Model may be created by a computer-aided-design (CAD) software application and stored as a CAD data file. Examples of suitable CAD software packages include I-DEAS (available from SDRC, Inc. of Milford, Ohio) and CATIA (available from International Business Machines [Corporation),]Corporation); however, any other suitable application could be used. The Medical Device Model could also, for example, be created through contact or non-contact three dimensional measurement/imaging of a physical device or model. In another embodiment, the medical device model 140 is created within the Mesh Generator 130 module itself.

Please amend the paragraph beginning on page 13 , lines 1-10, as follows:

The output of the Geometry Generator 120 is in the form of an Anatomy Model 240, which contains the geometric model of the anatomy scanned. The Anatomy Model 240 and the Medical Device Model 140 (containing the geometric model of the candidate medical device) are then received by the Mesh Generator 130 as input (usually as CAD files). The anatomy model may be a portion or an element of the anatomy scanned. Similarly, the medical device model may be a portion or [of] an element of the candidate medical device. This is useful for analyzing the interaction between a portion of a candidate device, such as a proximal stent in a TPEG, and a certain anatomical feature, such as tissue. The Mesh

Generator 130 then generates a finite element model incorporating both the anatomy model, whether idealized or actual, and the medical device model as represented by box 250.

Please amend the paragraph beginning on page 31, lines 7-15, as follows:

Line 138 in Figure 5D indicates that the initial value of the parameter rocompcyl is the value evaluated by the formula "[0.95*(min(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)-%RW6)." TRUEGRID understands that the min function has to be evaluated. The min function compares the value contained in each variable, in this case, contained in RCyl3 (e.g., contains 1), RCyl6 (contains 0.005), RCyl12_1 (contains 0.987), and RCyl12_2(contains 0.0002), and returns the content of the variable, which holds the least value—0.0002 (value contained in Rcyl12_2). Assuming the variable RW6 contains the value 0.18, TRUEGRID then evaluates the [rocompcly]rocompcyl variable to contain 0.95 * 0.0002 – 0.18, which equals to negative 0.17981. This value is thus the initial value of rocompcyl when initially processed and read by TRUEGRID.

Please amend the paragraph beginning on page 31, line 20, through page 32, line 2, with the following paragraph.

Referring to line 432, in Figure 5L, the term "include" indicates to TRUEGRID that when the condition as defined in line 431 is met, the istent.mts_nike_solid file is read. The contents of this include file could be added in the command file itself. For flexibility and readability, however, they were placed in a separate file. Programmers typically use include files, such as done in C or C++, for code control and ease of [maintenance]maintenance.

Please amend the paragraph beginning on page 33, lines 1-6, as follows:

To start, a TPEG designer first determines, in box 905A, the performance requirements desired, such as to secure an optimal structural integrity of the TPEG, to avoid potential health risks such as ruptures and endoleaks, or to have a smaller TPEG packaging. 3D volumetric data of the anatomy desired, for example, in this case a blood vessel, is then acquired at box 910A, using CT or MRI scanners. Alternatively, if 3D volumetric data are already available, such acquisition may be skipped and such 3D volumetric data may be obtained from the archive.

Please amend the paragraph beginning on page 34, line 20, through page 35, line

3, as follows:

If the fabricated prototype, however, does not meet the performance requirements, a "no" outcome at decision box 970A, the TPEG designer modifies the TPEG design or selects a new TPEG design, and repeats the steps as shown with the arrow to box 925A. If necessary, the process is repeated several times until the performance requirements and the final design [is]are obtained. A benefit of the invention is to reduce the number of "no" outcome at decision box 970A compared to a development process which uses only hardware prototypes for design verification.

Please amend the paragraph beginning on page 35, lines 4-9, as follows:

As discussed above, a proposed TPEG model may be evaluated against a number of anatomical features to determine the suitable range of conditions of an applicable TPEG model (e.g., size). Similarly, a set of anatomical features may be evaluated against a number of TPEG models to determine the type of suitable TPEG model for such set of anatomical [feature]features. Furthermore, an analysis of the stresses, strains, and deformations may be conducted on the medical device without interaction to certain anatomical features.

Please amend the paragraphs beginning on page 35, line 14, through page 36, line 3, as follows:

Visual display of the simulation is not necessary because a reading of the numerical representation of the stresses, strains, and deformation on the TPEG may guide a TPEG designer whether the performance requirements are met. However, visual display is often desirable because a visual representation of the stresses and strains, for example, red hot spots on the visual TPEG [model]model, can be easier to understand than mere numerical representations.

Figure 10 is similar to Figure 9A and illustrates a process to develop better-designed medical devices using in vitro features. In the first step as shown in 1005, a medical device designer, determines the performance requirements. The next step is to generate a geometry model of the in vitro model, step 1020A, (e.g., latex tube to represent an artery), using software tools, such as a CAD software or even TRUEGRID. The steps are then similar to those illustrated in Figure 9A. In another embodiment, the in vitro model such as a latex tube may be scanned to obtain [a] 3D volumetric data. Such acquired 3D volumetric data may also be modified by the medical device designer.

Please amend the paragraphs beginning on page 36, line 19, through page 37, line 13, as follows:

Next, a candidate TPEG, which is obtained typically from a model created using a CAD software, is selected by the physician (step 1125). (TPEG models may be created in advance and stored in a library in the system. At this point, the physician is determining which available TPEG design is best suited for that patient or individual). The Mesh Generator (130 in Fig. 1) then generates a mesh model incorporating both the blood vessel and the selected TPEG. A physician may then identify the material properties of the candidate TPEG and the blood vessel at step 1135. The material properties may have also been assigned during the previous step (i.e., the generation of the mesh model). Using a Stress/Strain/Deformation Analyzer (160 in Fig. 1), assuming that the load (150 in Fig. 1) and the materials model (170 in Fig. 1) are available to the Stress/Strain/Deformation Analyzer for input, a physician may then run the candidate TPEG to a stress/strain/deformation analysis (at step [640]1140) to determine if the candidate TPEG meets the surgical objectives.

If the candidate TPEG does not meet the procedural objectives, a "no" outcome at decision box 1155, a physician may decide to change the TPEG to be used in the procedure at step 1180 and repeat the process as shown by the arrow to box 1125. Based on the physician's judgment, if the candidate TPEG does meet the prcedural objectives, a "yes" outcome at decision box [655]1155, the physician then may decide whether to proceed with the planned TPEG implant procedure or not, at step 1160.

Please amend the paragraph beginning on page 40, lines 3-7, as follows:

In addition, although the modules of the system 105 (Figure 1), the Geometry Generator, the Mesh Generator, Stress/Strain/Deformation Analyzer, and the Visualization module, are shown in different boxes, depending on the software tools utilized their functions may overlap with each other. Some functions, for example, that are done by one module, e.g., the Mesh Generator, TRUEGRID, thus, may also be done by the Geometry Generator, MIMICS, or vice versa.

IN THE CLAIMS:

Please amend claims 1, 60, 71, 76, 89, 102 as follows:

1. (Amended) A system for analyzing the use of medical devices comprising:
a) geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature;
b) mesh generator that receives the said geometric model of said anatomical feature and the geometric model of a medical device, and generates a finite element model or mesh incorporating both said anatomical feature and said medical device; and
c) stress/strain/deformation analyzer that receives said mesh incorporating both said anatomical feature and said medical device, materials properties of said anatomical feature and said medical device, and load on said anatomical feature [and/orsaid]and/or said medical device, and simulates stresses, strains, and deformations of said medical device.

60. (Amended) A method as defined in claim [59]58 where said endovascaular prosthesis is a cardiovascular stent device.

71. (Amended) A method as defined in claim 70 further comprising the step of simulating [stresses.]stresses, strains, and deformations to point of failure of said medical device.

76. (Amended) A method as defined in claim 74 where said endovascular prosthesis is a [cariovascaula]cardiovascular stent device.

89. (Amended) A method as defined in claim [86]88 where said endovascular prosthesis is a transluminally placed endovascular graft.

102. (Amended) A method as defined in claim [99]101 where said endovascular prosthesis is a transluminally placed endovascular graft.